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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,761	02/21/2006	Takamasa Watanabe	0020-5502PUS1	6669

2292 7590 09/09/2009

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EXAMINER	
HADDAD, MAHER M	

ART UNIT	PAPER NUMBER
1644	

NOTIFICATION DATE	DELIVERY MODE
09/09/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/568,761	WATANABE ET AL.	
	Examiner	Art Unit	
	Maher M. Haddad	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 July 2009 and 20 August 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19,20 and 31-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-20 and 31-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

RESPONSE TO APPLICANT'S AMENDMENT

1. Applicant's amendment, filed 7/30/09 and 8/20/09, is acknowledged.

2. Claims 19-20 and 31-35 are pending and under consideration in the instant application.

3. Given that the Remarks filed 8/20/09 are substantially similar and can be used as a replacement for the amendment filed on 7/30/09, this Office Action will be in response to applicant's arguments, filed 8/20/09.

4. The following new ground of rejection is necessitated by the amendment submitted 8/20/09.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 19-20 and 32 stand and newly added claim 35 rejected under 35 U.S.C. 102(b) as being anticipated by U.S Pat. No. 6,423,501.

The `501 patent teaches a method of treating inflammatory condition in a mammal such as human (patient) comprising administering to the mammal an effective amount of an agent which induces CD81-mediated signal transduction. For example, the method can be used to treat inflammatory responses associated with disorders such inflammatory bowel disease (i.e., Crohn's disease and ulcerative colitis) (see col., 13, lines 34-45 in particular). The `501 patent teaches that agents described herein can be anything which binds to or interacts with CD81 and induces (i.e., activates) or enhances CD81-mediated signal transduction. For example, the agent can be a polyclonal or monoclonal antibody, such as an anti-CD81 antibody. In particular embodiments, the antibody is 5D1 or 1A12 (see col., 9, line 65 to col., 10, line 3 in particular). The `501 patent further teaches that injections of anti-CD81 yielded significant inhibition of PCA reactions (blocks a biological activity of CD81) (see FIG. 10B). The functional properties claimed in claim 32 are inherent.

While the prior art teachings may be silent as to the "shortened intestinal length is improved or treated by the method" and "wherein the loose stool or diarrhea is improved or treated by the method" per se; the method, the product used in the reference method are the same as the claimed method. Therefore these limitations are considered inherent properties. It is noted that a compound and all of its properties are inseparable; they are one and the same thing (see *In re Papesch*, CCPA 137 USPQ 43; *In re Swinehart and Sfiligoj*, 169) USPQ 226 (CCPA 1971)). Therefore, in the absence of evidence to the contrary, the anti-CD81 antibody administered by the `501 patent, would "shortened intestinal length is improved or treated by the method" and "wherein the loose stool or diarrhea is improved or treated by the method".

Since the office does not have a laboratory to test the reference antibodies, it is applicant's burden to show that the reference anti-CD81 antibody does not "shortened intestinal length is improved or treated by the method" and "wherein the loose stool or diarrhea is improved or treated by the method" recited in the claim. See In re Best, 195 USPQ 430, 433 (CCPA 1977); In re Marosi, 218 USPQ 289, 292-293 (Fed. Cir. 1983); and In re Fitzgerald et al., 205 USPQ 594 (CCPA 1980).

The reference teachings anticipate the claimed invention.

7. Claims 19-20 and 32 stand and newly added claim 35 is rejected under 35 U.S.C. 102(b) as being anticipated by WO 98/25647 (IDS ref. No. BJ).

The `647 publication teaches a method of treating inflammatory condition in a mammal such as human (patient) comprising administering to the mammal an effective amount of an agent which induces CD81-mediated signal transduction. For example, the method can be used to treat inflammatory responses associated with disorders such inflammatory bowel disease (i.e., Crohn's disease and ulcerative colitis) (see col., 26, lines 12-22 in particular). The `501 patent teaches that agents described herein can be anything which binds to or interacts with CD81 and induces (i.e., activates) or enhances CD81-mediated signal transduction. For example, the agent can be a polyclonal or monoclonal antibody, such as an anti-CD81 antibody. In particular embodiments, the antibody is 5D1 or 1A12 (see Pg. 19, line 3-9 in particular). The `647 publication further teaches that injections of anti-CD81 yielded significant inhibition of PCA reactions (blocks a biological activity of CD81) (see FIG. 10B). The functional properties claimed in claim 32 are inherent.

While the prior art teachings may be silent as to the "shortened intestinal length is improved or treated by the method" and "wherein the loose stool or diarrhea is improved or treated by the method" per se; the method, the product used in the reference method are the same as the claimed method. Therefore these limitations are considered inherent properties. It is noted that a compound and all of its properties are inseparable; they are one and the same thing (see *In re Papesch*, CCPA 137 USPQ 43; *In re Swinehart and Sfiligoj*, 169) USPQ 226 (CCPA 1971)). Therefore, in the absence of evidence to the contrary, the anti-CD81 antibody administered by the `501 patent, would "shortened intestinal length is improved or treated by the method" and "wherein the loose stool or diarrhea is improved or treated by the method".

Since the office does not have a laboratory to test the reference antibodies, it is applicant's burden to show that the reference anti-CD81 antibody does not "shortened intestinal length is improved or treated by the method" and "wherein the loose stool or diarrhea is improved or treated by the method" recited in the claim. See In re Best, 195 USPQ 430, 433 (CCPA 1977); In re Marosi, 218 USPQ 289, 292-293 (Fed. Cir. 1983); and In re Fitzgerald et al., 205 USPQ 594 (CCPA 1980).

The reference teachings anticipate the claimed invention.

Applicant's arguments, filed 8/20/09, have been fully considered, but have not been found convincing.

Applicant submits that the '501 does not disclose the shortening of the intestinal length associated with IBD or the loose stool or diarrhea associated with IBD. An antibody to a single B cell surface marker out of a laundry list of B cell surface markers when administered to a subset of patients from a laundry list of possible patients does not put the public in possession of a specific treatment for a specific disease in any meaningful way. That said treatment would also have specifically claimed results is also not disclosed in any meaningful way.

It is the Examiner's position that a patent is an enabling reference for all that it teaches. Further, the teachings of the `501 patent is not limited to a specific molecule, but rather to the patent as a whole. The identity required for anticipation is between the claimed subject matter and the subject matter disclosed by the reference; identity does not require the reference to disclose the same subject matter as described in the specification. *Kalman v. Kimberly Clark Corp*. 218 USPQ 781 (Fed. Cir. 1983).

While the prior art teachings may be silent as to the "shortened intestinal length is improved or treated by the method" and "wherein the loose stool or diarrhea is improved or treated by the method" per se; the method, the product used in the reference method are the same as the claimed method. Therefore these limitations are considered inherent properties. It is noted that a compound and all of its properties are inseparable; they are one and the same thing (see *In re Papesch*, CCPA 137 USPQ 43; *In re Swinehart and Sfiligoj*, 169) USPQ 226 (CCPA 1971)). Therefore, in the absence of evidence to the contrary, the anti-CD81 antibody administered by the `501 patent, would "shortened intestinal length is improved or treated by the method" and "wherein the loose stool or diarrhea is improved or treated by the method".

The Examiner discounts the fact that there was no satisfactory treatment for IBD at the filing date. The Examiner states that "evidence of secondary considerations.., is irrelevant to 35 U.S.C. § 102." (Office Action, page 5). Applicants submit that this is not evidence of secondary considerations, but is instead evidence that the public was not in possession of the claimed invention prior to the filing of the present application. Essentially, these references illustrate that one of skill in the art would not have combined the publication's description of the invention with his own knowledge to obtain the present invention. As the Examiner is allowed to use a secondary reference to prove that the primary reference contains an enabled disclosure (In re Donohue, 766 F.2d 531,226 USPQ 619 (Fed. Cir. 1985); cited in MPEP § 2131.01), Applicants should be allowed to provide a reference to show that the primary reference does not contain an enabled disclosure. Applicant submits that the '501 and '647 do not contain enabling disclosures for the claimed method.

However, The Examiner's position is that the teachings of the `501 and '647 indicate that the public is in possession of the claimed subject matter prior to the filing of the present application. "The reason is that section 112 "provides that the specification must enable one skilled in the art to 'use' the invention whereas [section] 102 makes no such requirement as to an anticipatory disclosure." *Hafner*, 410 F.2d at 1405; *see 1* Donald S. Chisum, *Chisum on Patents §* 3.04[1][c] (2002); *see also In re Cruciferous Sprout Litig*., 301 F.3d 1343, 1349-52 (Fed.Cir.2002) (finding

anticipation where applicant sought a patent based on a new use for a previously disclosed method)."

8. Claims 19-20 and 31-32 stand and newly added claim 35 is rejected under 35 U.S.C. 102(b) as being anticipated by Curd et al (WO 00/67796).

Curd et al teach treatment of inflammatory bowel disease, Crohn's disease and ulcerative colitis with anti-CD81 antibody (see published claims 1, 2, 3, 6) in human (published claim 7). The various functional activities recited in the claims are inherently found in said method the method taught by Curd et al teaches in vivo administration of the same antibody recited in the claims to treat the same disease recited in the claims. Curd et al teach the claimed antibody fragments (see page 4, lines 38-40).

While the prior art teachings may be silent as to the "shortened intestinal length is improved or treated by the method" and "wherein the loose stool or diarrhea is improved or treated by the method" per se; the method, the product used in the reference method are the same as the claimed method. Therefore these limitations are considered inherent properties. It is noted that a compound and all of its properties are inseparable; they are one and the same thing (see *In re Papesch*, CCPA 137 USPQ 43; *In re Swinehart and Sfiligoj*, 169) USPQ 226 (CCPA 1971)). Therefore, in the absence of evidence to the contrary, the anti-CD81 antibody administered by the `501 patent, would "shortened intestinal length is improved or treated by the method" and "wherein the loose stool or diarrhea is improved or treated by the method".

Since the office does not have a laboratory to test the reference antibodies, it is applicant's burden to show that the reference anti-CD81 antibody does not "shortened intestinal length is improved or treated by the method" and "wherein the loose stool or diarrhea is improved or treated by the method" recited in the claim. See In re Best, 195 USPQ 430, 433 (CCPA 1977); In re Marosi, 218 USPQ 289, 292-293 (Fed. Cir. 1983); and In re Fitzgerald et al., 205 USPQ 594 (CCPA 1980).

The reference teachings anticipate the claimed invention.

Applicant's arguments, filed 8/20/09, have been fully considered, but have not been found convincing.

Applicant submits that the Examiner rejects claims 19-20, and 31-32 under 35 U.S.C. § 102(b) as being anticipated by Curd et al. (WO 00/67796) (hereinafter Curd). Like '501 and '647 above, Curd does not provide any examples of treating IBD, does not provide any specific antibodies, and does not in any way put the public in possession of the claimed method in such a manner that one of skill would be able to obtain the present invention from this reference.

However, the Examiner noted that the `796 publication claims applicant's subject matter. Yet, Applicant argues that the reference is not enabled and the public is not in possession of the claimed method. The is no requirement under 102 to be reduced to practice in order to anticipate.

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> *(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.*

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 31 and 33-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S Pat. No. 6,423,501 or WO 98/25647 or WO 00/67796 in view of and Owens *et al* (1994).

The teachings of Pat. No. 6,423,501 or WO 98/25647, WO 00/67796 publication have been discussed, supra.

The claimed invention differs from the reference teachings only by the recitation of and Fab, F(ab`)2 or Fv or scFv in claim 31 and the dosage recited in claims 33-34.

Owens *et al* teach the modification of murine antibodies such as a single chain antibody, a Fab fragment, a $F(ab')_2$ fragment. Owens *et al* further teach that antibody fragments are the reagents of choice for some clinical applications, and the chimeric antibodies offers the ability to mediate antigen-dependent cytotoxicity and complement –dependent cytotoxcity (see the entire document).

Claims 33-34 are included because it is well settled that "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." *In re Boesch*, 617 F.2d 272, 276, 205 USPQ 215,219 (CCPA 1980). Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955). see MPEP §§ 2144.05 part II A. The determination of the optimal intervals of treatment is well within the purview of one of ordinary skill in the art at the time the invention was made and lends no patentable import to the claimed invention. The duration of treatment, the specific rout of administrations and like factors are within the knowledge and expertise of the medical practitioner.

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to modify the anti–CD81 antibody taught by 6,423,501 or WO 98/25647 to Fab or F(ab')2 fragments taught by Owens et al.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so because the antibody fragments are the reagents of choice for some clinical applications and the chimaeric antibodies offers the ability to mediate antigen-dependent cytotoxicity and complement-dependent cytotoxcity as taught by Owens *et al.*

From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Applicant's arguments, filed 8/20/09, have been fully considered, but have not been found convincing.

Applicant submits that none of primary references contain enabling disclosure.

It is the Examiner's position that the prior art is enable for all it teaches.

11. No claim is allowed.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (571) 272-0845. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

September 1, 2009

/Maher M. Haddad/
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